Remarks

A. Priority Claim

The Examiner asserted that Applicant has not complied with a condition for receiving the benefit of an earlier filing date under 35 U.S.C. § 119(e). A new paragraph has been added before the first paragraph of the specification which refers to the prior application. Thus, Applicant has now complied with the requirements of 35 U.S.C. § 119(e). Applicant respectfully acknowledges that a priority claim to the aforementioned application is present in the oath.

B. Presentation of Claims 23-31

During a telephone conversation with Examiner Ron Schwadron on May 4, 2005, the Examiner agreed to allow Applicant to cancel Claims 21 and 22 and reinstate the subject matter of original Claims 1-9. New Claims 23-31 reflect the subject matter originally presented Claims 1-9. Thus, no new matter has been added to the application. While Applicant reserves the right to continue prosecution on Claims 10-20 in the present application or in a later-filed divisional or continuing application, only Claims 23-31 are currently under consideration.

C. Rejection of Claims 21-22 under 35 U.S.C. § 112

Because Claims 21-22 have been cancelled from the application, this rejection is no longer applicable.

D. Rejection of Claims 21-22 under 35 U.S.C. § 102(b)

Though the Examiner rejected Claims 21-22 under 35 U.S.C. § 102(b) as anticipated by Tokoro as evidenced by Zhang and Lipford, Applicant will respond to the rejection in light of reinstated Claims 23-31. Tokoro relates to a method that includes

injecting hens with pathogens that cause intestinal diseases in neonatal mammals. In response to the immunization, the hens produce antibodies that are specific for the injected pathogens. The antibodies are present in eggs that are laid by the hens. The antibodies may then be extracted from the eggs and used to treat the particular intestinal disease.

Despite the fact that transfer factors have been known and studied since the late 1940's, the Tokoro reference lacks any discussion of transfer factors. Tokoro does not teach that transfer factor is present in its hen eggs but, rather, that a "transfer factor-like component" is present in the eggs. By using the term "like" in the description of the "transfer factor-like component", Tokoro teaches that something other than transfer factor was actually present in the eggs and, thus, Tokoro cannot anticipate the present invention. In fact, because Tokoro teaches that something other than transfer factor is present in the invention, it actually teaches away from the subject matter recited in the claims of the present application.

"Transfer factor-like" is a term of art that indicates a substance which has transfer factor-like activity, but is not actually transfer factor. The term "transfer factor-like" is described in Dunnick, W., *et al.*, "*Lack of Antigen Fragments in Guinea Pig Transfer Factor-like Activity*," Clin. Immunol. and Immunopathol. 17:55-65 (1980). Dunnick refers to the substance evaluated therein, which has transfer factor-like activity, as "TFLA". Based on the experiments described in the reference, Dunnick concludes that superantigenicity, a characteristic of transfer factor (p. 55), "cannot explain the activity of TFLA." (Dunnick, p. 65). Dunnick states that "[w]hereas transfer factor and TFLA are structurally similar . . . and the tests for the two are related, no

direct relationship has been established between TFLA and *in vivo* transfers of cellular immunity." (Dunnick, pg. 65). It has long been known that transfer factors are capable of transferring cellular immunity *in vivo*. Thus, it is clear that transfer factor is different from the "transfer factor-like component" of Tokoro and that a "transfer factor-like component" will not necessarily transfer immunity. Therefore, Tokoro cannot anticipate the present invention.

In its disclosure, Tokoro even implies that its "transfer factor-like component" is not actually transfer factor. The Tokoro reference states, "the immunological functions of the transfer factor-like component . . . are not known." (Tokoro, col. 7, lines 44-47). In contrast, the immunological functions of transfer factor are known. Additionally, Tokoro states that "[t]here is a possibility that a part of the transfer factor-like component is the same as the food factor described in [U.S. Pat. No. 4,402,938]." (Tokoro, col. 7, lines 51-54). If, as Tokoro asserts, there is a possibility that its transfer factor-like component is the same as the food factor described in U.S. Pat. No. 4,402,938, it cannot also be transfer factor. This statement is further evidence that even Tokoro does not believe that its "transfer factor-like component" is truly transfer factor.

In summary, Applicant submits that the claims and specification are now in condition for allowance. It is respectfully submitted that claims 1-9 are patentably distinct over the references cited by the Examiner and meet all other statutory requirements. Therefore, reconsideration of the rejections in the Office Action is respectfully requested. The Examiner is invited to telephone the undersigned should any issues remain after the consideration of this response.

Please charge any additional fees that may be required to Deposit Account No. 50-2548.

Respectfully requested,

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June 23, 2005
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Dopson, et al.	)	Group Art Unit: 1644
Serial No.:	09/954,961	)	Examiner: Ronald D. Schwadron
Filed:	September 18, 2001	)	Deposit Account: 50-2548
Title:	Transfer Factor Composition and Process for Producing Same	)	Docket No.: 20663/09003

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL ARGUMENTS WHICH CORRESPOND TO APPLICANT'S REQUEST TO PROVOKE AN INTERFERENCE UNDER 37 C.F.R §1.607

Dear Sir:

Applicant presented a request to provoke an interference proceeding under 37 C.F.R. §1.607 with U.S. Patent No. 6,468,534 to Hennen, *et al.* (Hennen) on October 21, 2003. The following remarks and arguments are supplemental to Applicant's original request to provoke an interference. The Commissioner is hereby authorized to charge any additional fees which may be required to Deposit Account 50-2548.

I. Identification of Patent with which Applicant Request to Provoke an Inteference

Applicant hereby identifies U.S. Patent No. 6,468,534 to Hennen, *et al.* as claiming the same patentable invention as the present application, U.S. Serial No. 09/954,961 to Dopson.

II. Proposed Count

A method for obtaining transfer factor, comprising:

exposing a non-mammalian source animal to at least one antigenic agent that will cause said non-mammalian source animal to elicit a T-cell mediated immune response;

permitting said non-mammalian source animal to elicit a T-cell mediated immune response to said at least one antigenic agent;

collecting at least one egg from said non-mammalian source animal following said T-cell mediated immune response, said at least one egg including transfer factor that transfer cellular immunity to a mammal in vivo and that includes transfer factor molecules having molecular weights of about 4,000 Da to about 5,000 Da.

III. Identification of Patent Claims That Correspond to the Proposed Count

The Hennen patent issued with Claims 1-30. Applicant hereby identifies Claims 1-30 of Hennen as corresponding to the above-proposed count. Claim 1 of Hennen is identical to the proposed count and claims 2-30 of Hennen are directed to the same patentable invention.

IV. Identification of Applicant's Claims That Correspond to the Proposed Count

The present application to Dopson contains Claims 23-31. Applicant hereby identifies currently pending Claims 23-31 of Dopson as corresponding to the proposed count. The claims in the application "need not be, and most often will not be, identical to a claim in the patent." 37 C.F.R. § 1.606. Claims 23-31 of the Dopson Application define the same patentable invention as the identified count.

V. Application of the Terms of Applicant's Claims to the Proposed Count

Applicant submits that each limitation of Dopson's Claim's 23-31 correspond to the proposed count, including, but not limited to, the reasons stated below.

a) Limitation #1 of Dopson Claim 23: "A process for producing transfer factor, said process comprising the steps of"

The Claim 23 limitation of "A process for producing transfer factor, said process comprising the steps of" conveys the same meaning as the proposed count language of "A method for obtaining transfer factor, comprising".

b) Limitation #2 of Dopson Claim 23: "immunizing a female bird"

The Claim 23 limitation of "immunizing a female bird" corresponds substantially to the proposed count language of "exposing a non-mammalian source animal". The phrases each anticipate and make obvious the other.

c) Limitation #3 of Dopson Claim 23: "with a sufficient quantity of at least one selected antigen"

The Claim 23 limitation of "with a sufficient quantity of at least one selected antigen" is the same as the proposed count language of "to at least one antigenic agent". Both phrases substantially correspond to the addition of (*i.e.* immunization with) an antigen or antigenic agent.

d) Limitation #4 of Dopson Claim 23: "so that said bird develops immunity to said at least one antigen;"

The Claim 23 limitation of "so that said bird develops immunity to said at least one antigen;" substantially corresponds to the proposed count language of "that will cause said non-mammalian source animal to elicit a T-cell mediated immune response;"

The Claim 23 limitation of "develops immunity" to an antigen would be understood by one of skill in the art as inherently the same as eliciting a "T-cell mediated immune response". Many scientific publications, treatises and patents support the idea that developing immunity to an antigen will necessarily involve a T-cell mediated immune response.

For example, the Hennen patent itself teaches in col. 2, lines 4-6 that "T-cells are primarily responsible for the secondary, or delayed-type hypersensitivity, immune response to a pathogen or antigenic agent." Likewise, Fundenberg, H., *et al.*, *Annual Review of Pharmacology and Toxicology*, Vol. 29, p. 5 (1989), supports the idea that developing immunity to an antigen is a T-cell mediated immune response by stating, "[w]e now reserve the term TF (*i.e.* transfer factor) for the components of DLE that

transfers T-lymphocyte responses in an antigen-specific fashion. . . ." (*emphasis added*) Also, Rudin, N., Dictionary of Modern Biology, Barron's Educational Services, p. 363 (1997) describes T-cells as essential participants in the cell-mediated immune response.

In addition, the Dopson application describes in Example 1 a delayed-type hypersensitivity assay for testing chickens to determine if they had developed immunity after injection of an antigen. One of skill in the art will understand that the disclosure of a delayed-type hypersensitivity assay would inherently support a disclosure of a T-cell mediated immune response because such an assay is known to be a measure of a T-cell response. See *e.g.*, U.S. Patent to Hennen, *et al.* at col. 2, lines 4-6; U.S. Patent No. 6,576,428 to Assenmacher, *et al.*, at col. 4, lines 66-67, "T cells play important roles in autoimmunity, inflammation, cytotoxicity, graft rejection, allergy, *delayed-type hypersensitivity,* IgE-mediated hypersensitivity, and modulation of the humoral response" (*emphasis added*); and Lodish, H., *et al.*, *Molecular Cell Biology*, 3rd Edition, Scientific American Books, Inc., Chap. 27, p. 1331 (1997) (certain mobilization of phagocytes by T_H-cells are called delayed-type hypersensitivity responses because they can take hours or days to develop).

e) Limitation #5 of Dopson Claim 23: "after said bird develops immunity to said at least one antigen,"

The Claim 23 limitation of "after said bird develops immunity to said at least one antigen," corresponds to the proposed count language of "permitting said non-mammalian source animal to elicit a T-cell mediated immune response to said at least

one antigenic agent;". The "bird" limitation in Dopson's Claim 1 corresponds to the "non-mammalian source animal" in the proposed count. Likewise, the "immunity" limitation in Dopson's Claim 1 corresponds to the "T-cell mediated immune response" in the proposed count for the same reasons recited above with respect to limitation #4.

f) Limitation #6 of Dopson Claim 23: "collecting eggs laid by said bird;"

The Claim 23 limitation of "collecting eggs laid by said bird;" corresponds substantially to the proposed count language of "collecting at least one egg from said non-mammalian source animal following said T-cell mediated immune response,".

g) Limitation #7 of Dopson Claim 23: "and treating said eggs to recover transfer factor therefrom."

The Claim 23 limitation of "and treating said eggs to recover transfer factor therefrom" corresponds substantially to the proposed count language of "said at least one egg including transfer factor that transfer cellular immunity to a mammal in vivo and that includes transfer factor molecules having molecular weights of about 4,000 Da to about 5,000 Da." The transfer factor recovered from eggs in Dopson's Claim 23 is disclosed in the Dopson specification as being capable of transferring cellular immunity to a mammal *in vivo* as required by the proposed count. See Dopson, U.S. Serial No. 09/954,961, p. 2, lines 4-13 and p. 9, lines 4-9.

Finally, Applicant's specification discloses that transfer factors generally have molecular weights that range from approximately 3,000 – 6,000 Da. See Dopson, U.S.

Serial No. 09/954,961, p. 2, lines 25-26. Thus, Applicant's range fully supports and encompasses the about 4,000 to about 5,000 Da range of the proposed count.

Applicant's Claims 24 - 31 also correspond to the proposed count as obvious variants the count.

VI. Requirements of 35 U.S.C. §135(b)

The Hennen Patent was issued on October 22, 2002 and was filed on September 21, 2000. Therefore, the Hennen Patent never published and the 1-year date of 35 USC §135(b) should be calculated from October 22, 2002. Applicant's Request for Interference were filed on October 21, 2003. Thus, Applicant presented claims that correspond substantially to at least one of the claims of the Hennen Patent prior to 1 year from the date it was issued.

VII. Argument

In light of the foregoing application of the terms of Applicant's claims to the proposed count, Applicant submits that each limitation of Dopson's Claims 23 - 31 substantially correspond to the proposed count.

An interference will be declared if both parties to the interference have at least one claim that defines the "same patentable invention". 37 C.F.R. § 1.601(i). The phrase "same patentable invention" has been interpreted as requiring a "two-way test" to determine whether two parties claim the same patentable invention. Under this "two-way test", the claimed invention of the patentee must anticipate or render obvious the claimed invention of the applicant and the claimed invention of the applicant must also anticipate or render obvious the claimed invention of the patentee. *Eli Lilly & Co. v. Bd.*

of Regents of the U. of Wash., 334 F.3d 1264, 1269, 67 USPQ 2d 1161 (Fed. Cir. 2003).

Under this analysis, an interference should be declared in this circumstance. The main differences between Applicant's claims and Patentees claims are that Applicant claims a "bird" while Patentee claims a "non-mammilian animal source" and Applicant claims an "immunity" while Patentee claims a "T-cell mediated immune response". These differences do not create patentably distinct inventions. Instead, the phrase "immunizing a bird" with an antigen anticipates the phrase "exposing a non-mammalian animal source" to an antigen. Similarly, the phrase "exposing a non-mammalian animal source" to an antigen anticipates the phrase "immunizing a bird" with an antigen. The "immunity" of Applicant's claims anticipates the "T-cell mediated immune response" of Patentee's claims and the "T-cell mediated immune response" of Patentee's claims anticipates the "immunity" of Applicant's claims. Because the "two-way test" is satisfied, it is respectfully requested that the Examiner declare an interference between Dopson and U.S. Patent No. 6,468,534 to Hennen, *et al.*

The Examiner is invited to telephone the undersigned should issues remain after consideration of the present Request to permit early resolution of same. Please charge any additional fees required by this Response to Deposit Account No. 50-2548.

Respectfully requested,

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Date

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